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By: Juan Visek

PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: ERIC KUO

Application No.: 10/612,239

Filed: July 1, 2003

For: DENTAL APPLIANCE SEQUENCE
ORDERING SYSTEM AND METHOD

Confirmation No. 3324

Examiner: WILSON, JOHN J.

Technology Center/Art Unit: 3732

**PRE-APPEAL BRIEF REQUEST
FOR REVIEW**

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants offer this Pre-Appeal Brief Request for Review, in conjunction with a Notice of Appeal (attached separately), for review of the present application under the Patent Pre-Appeal Brief Conference Pilot Program.

STATUS OF THE CLAIMS/GROUNDS OF REJECTION UNDER REVIEW

Claims 1, 19-21, 27-29, and 37-48 are currently pending. Claims 1 and 37 have been allowed. Claims 19-21, 27-29, and 38-48 stand rejected under numerous grounds as set forth below. For sake of clarity with respect to the current status of the claims, Applicants point out that amendments to the claims were submitted under 37 CFR § 1.116 in Applicants' Response filed 6/13/2007. These amendments were denied entry pursuant to the Advisory Action mailed 7/6/2007. Applicants further submitted a second amendment under 37 CFR § 1.116 in Applicants' response filed 7/24/2007, canceling claims 14-16 and 30-36 in order to narrow the issues under review/appeal. As such, the current status of the claims will be as presented in the listing of the claims submitted in Applicants' response filed 7/24/2007. The claims are further attached hereto as Appendix A. The only pending rejections, of which review is herein requested, include those rejections as listed in the "Argument" section below.

ARGUMENT

Claims 45 and 46 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

In the Final Office Action mailed 2/13/07 (page 2), the sole basis for the present rejection of the claims was that "[n]o examples of color indicia comprising a dissolvable dye that dissolves in water or one that dissolves in air has [sic] be[en] given..." Applicants have pointed out, however, that absence

of specific working examples is not dispositive as to alleged lack of enabling disclosure (see, e.g., MPEP § 2164.01(a)). As set forth in MPEP § 2164.02, "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." Further stated, "In other words, lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement." MPEP § 2164.02, emphasis added. Applicants have further pointed out that known/commercially available dyes dissolvable dyes are available for use according to the present invention, and choosing a dye from among known/available dissolvable dyes would require no undue experimentation. As such, the Examiner has failed to establish any evidence, let alone meet the requisite burden of proof, to indicate lack of enablement.

In the Advisory Action mailed 7/6/2007, rather than provide any objective evidence or rationale to support the alleged lack of enablement, the Examiner incorrectly stated that "it is [A]pplicant's duty to supply support for the statement that one of ordinary skill in the art [sic] would find a dye to use as claimed without undue experimentation." The Examiner's attempt to place the initial burden on the Applicant is a clear error of law, however, as "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." *In re Wright*, 999 F.2d 1557, 1562 (Fed.Cir. 1993); MPEP §2164.04. As set forth above, merely citing a lack of working examples is insufficient to meet the Examiner's burden and, therefore, Applicants are under no obligation to provide additional evidence. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claim 47 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is alleged that the original disclosure contains no teaching of using a "peel-away" removable wrapper (Final Office Action, pages 2-3). Applicants have already pointed out where such disclosure can be found in the originally filed application including, for example, at Figure 7C and the accompanying disclosure at page 9, lines 13-18, where a "peel-away wrapper 62" is specifically described (see, e.g., Applicants' response filed 6/13/2007, pp9-10). As such, written description support has been provided in the originally filed specification. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 19-21 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (5,975,893) in view of Klein (4,038,753). Neither of the cited references, alone or in combination, teach a non-numerical indicia designating an order in which each of the plurality of dental

appliances are to be worn by a patient to provide dental treatment, as recited in claim 19, thereby precluding *prima facie* obviousness.

Chishti teaches a system for repositioning teeth including a plurality of individual appliances. While Chishti teaches numerical indicia for order of use, Chishti does not teach non-numerical indicia designating an order of use. Klein fails to teach non-numerical indicia having information designating order of use. The Examiner has cited the term "A-1-REG", but this is a combination of numbers and letters on the central ring of the Klein article, and appears indicative of central ring size rather than indicating or in any way suggesting order of use. Additionally, nothing on the Klein article includes information indicating which of attached intraoral tension rings are to be used before any others. In fact, since all the rings appear identical, order of use would seem irrelevant in the teachings of Klein. Furthermore, the present instance is not merely a matter of employing the same structure of Klein for a different use (e.g., different mental interpretation and/or intended use) as alleged. The structure of Klein (e.g., "A-1-REG") is different from the structure required by the claim, and the Klein "A-1-REG" structure would actually appear incapable of being used as non-numerical indicia designating an order of use. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 27-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* in view of Klatt (U.S. Pub. No. 2003/0136698). Neither cited reference, alone or in combination, teach each and every element of the claimed invention, including a package including a plurality of geometrically distinct dental appliances positioned in an arrangement within the package which indicates an order of usage, as recited in current claim 27.

Klatt teaches a stack of identical (e.g., not geometrically distinct) blister cards in a package with numerical indication of the number of days left in a drug treatment regime. The stacking of Klatt is taught for the purpose of visualizing length of treatment and drug regime duration, with no indicia or information indicating order of use. In fact, as the blister cards of Klatt are identical, order of usage would be irrelevant to the system of Klatt. Thus, Klatt fails to teach geometrically distinct articles/appliances positioned in an arrangement within the package, the positioning having information which indicates an order of usage.

The Examiner disregards the fact that Klatt teaches stacking identical blister cards based on the allegation that the term "geometrically distinct" is not defined by the present disclosure, and points out that the blister cards of Klatt are geometrically located in different locations. Applicants respectfully submit that the Examiner's position has no reasonable basis as the Examiner's interpretation would be

precluded by the plain meaning of the term "geometrically distinct appliance", which clearly does not refer to relative positioning or the obvious fact that two different objects cannot occupy the same space at the same time. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 38 and 39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* in view of Wong *et al.* (6,206,695) and Rohlcke *et al.* (5,326,259). The cited references fail to teach each and every element of the claimed invention - in particular, fail to teach non-numeric indicia comprising information designating an order of use, e.g., non-numeric indicia comprising one or more cutouts so that each polymeric shell has a different cutout pattern, as recited in claim 38.

Applicants disagree that Wong teaches color (or any non-numerical indicia) to indicate order of use, as alleged. Wong teaches orthodontic reamers with colored handles, where the different colored handles are designed to allow the practitioner to more easily distinguish the differently sized endodontic reamers and avoid confusion between different sized reamers that may be otherwise difficult to distinguish upon visual inspection. No specific order of use of the tools is prescribed by the color designations, instead a particular reamer size selected for use on a patient is determined by the practitioner based the doctor's discretion.

Rohlcke teaches marking metal orthodontic brackets to identify their orientation (e.g., top side, bottom side) when attached to individual teeth. No marking or indicia is taught by Rohlcke as to order of use and, in fact, no logical connection exists between the teachings of Rohlcke (e.g., markings for bracket orientation) and Wong (e.g., color to indicate reamer size). Neither reference teaches color or any non-numeric indicia whatsoever including information indicating order of use of anything. As such, the cited references fail to teach non-numeric indicia comprising one or more cutouts so that each polymeric shell has a different cutout pattern, as recited in claim 38. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 40 and 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* in view of Wong *et al.* and Martin (6,884,071). The combination of Chishti and Wong is overcome for at least a similar rationale as set forth above. Martin teaches using electronically legible codings (bar codes) as containing information about the mixing time, the material, the manufacturer and/or the expiration date (see, Martin at col. 7, lines 28-29). Martin fails to teach non-numeric indicia having a structure including information regarding order of use. Neither Wong nor Martin teaches non-numeric indicia having the structure defined by the claims - i.e., non-numeric indicia designating order of use. As such, the cited references fail to teach each and every element of the claimed invention. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 42 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* in view of Wong *et al.* and Martin as applied to claim 40, in further view of Morris (5,923,001). The combination of Chishti, Wong, and Martin as applied to claim 40 is overcome for at least the reasons set forth above. While Morris teaches radio frequency identification tags, Morris fails to teach using such tags, or any other indicia, structurally defined to include information indicating order of use. As such, Morris fails to provide the teachings that are missing from Chishti, Wong, and Martin and, therefore, the cited references, either alone or in combination, fail to teach each and every element of the claimed invention. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 44 and 47 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* in view of Wong *et al.* The combination of Chishti and Wong is overcome for at least a similar rationale as set forth above. Wong teaches orthodontic reamers having different colored handles to avoid confusion between closely, but differently, sized reamers. But the colors do not contain information regarding order of use, and, therefore, Wong fails to teach the structural element of claims 44 and 47 - i.e., a color indicia comprising information designating an order in which each of the plurality are to be worn by a patient. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Claims 45 and 46 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* in view of Wong *et al.* as applied to claim 44 above, and further in view of Bates *et al.* (U.S. Patent No. 5,411,295). The combination of Chishti and Wong as applied to claim 44 is overcome for at least the reasons set forth above. Bates teaches a water dissolvable ink as a tamper-evident label, but Bates does not teach a water dissolvable ink structurally defined so as to indicate order of use of anything and, therefore, fails to provide the teachings that are missing from Chishti and Wong. Accordingly, Applicants respectfully request that these rejections be withdrawn.

CONCLUSION

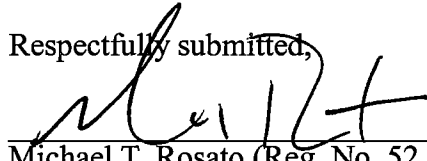
In view of the foregoing, Applicants believe all currently pending claims are in condition for allowance.

Dated: _____

8/10/2007

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Respectfully submitted,



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APPENDIX

1. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, and each of the polymeric shells having at least one terminal tooth cavity, wherein the indicia comprises a terminal tooth cavity of differing length in each of the polymeric shells.
- 2-18. (Canceled)
19. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances to be worn by a patient to provide dental treatment, each of the plurality of dental appliances having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement;
a framework, wherein each of the plurality of dental appliances are removably attached to a portion of the framework; and
a non-numeric indicia designating an order in which each of the plurality of dental appliances are to be worn by a patient to provide dental treatment.
20. (Original) A system as in claim 19, wherein each of the plurality of dental appliances comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.
21. (Previously presented) A system as in claim 19, wherein the indicia comprises at least one marking on the framework or an appliance indicating the order in which the appliances are to be worn by a patient.
22. - 26. (Canceled)
27. (Previously presented) A package of dental appliances comprising:
a package including a plurality of geometrically distinct dental appliances positioned in an arrangement within the package which indicates an order of usage, the plurality of dental appliances

comprising a plurality of geometrically distinct successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from an initial arrangement toward a successive arrangement.

28. (Original) A package as in claim 27, wherein each of the appliances comprises a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, the plurality of appliances including a first shell to be worn by the patient to reposition the teeth from the one arrangement to the successive arrangement and a second shell to be worn by the patient to reposition the teeth from the successive arrangement to another successive arrangement.

29. (Previously presented) A package as in claim 28, wherein the arrangement of appliances within the package comprises stacking of the appliances in an order of usage.

30-36 (Canceled)

37. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, and each of the polymeric shells having a height, wherein the indicia comprises a different height in each of the polymeric shells.

38. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern.

39. (Previously presented) A system as in claim 38, wherein the cutout comprises a notch in an edge of the appliance.

40. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the indicia comprises a computer readable element.

41. (Previously presented) A system as in claim 40, wherein the computer readable element comprises a barcode.

42. (Previously presented) A system as in claim 40, wherein the computer readable element is readable by wireless means.

43. (Previously presented) A system as in claim 42, wherein the wireless means utilizes radiofrequency.

44. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances comprising color indicia designating an order in which each of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the color indicia comprises a dissolvable dye.

45. (Previously presented) The system of claim 44, wherein the dye dissolves following removal of an appliance from a package and contact with air.

46. (Previously presented) The system of claim 44, wherein the dye dissolves following contact with a liquid.

47. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances comprising color indicia designating an order in which each of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the color indicia comprises a peel-away wrapper removably attached to an appliance.

48. (Previously presented) The system of claim 19, wherein the indicia comprises an arrangement of the appliances on the framework which indicates order of usage.